

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Edward J. Kaplan

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Examiner: Jagadishwar Rao Samala

For: *FLEXIBLE AND/OR ELASTIC BRACHYTHERAPY SEED OR STRAND*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

37 C.F.R. 41.202 SUGGESTION OF AN INTERFERENCE

37 C.F.R. 41.202(a)(1)

The Applicant seeks an interference between the present application and pending applications U.S.S.N. 11/187,411 and U.S.S.N. 11/489,895, naming Lamoureux et al. as inventors (herein after referred to as “the ‘411 application” and “the ‘895 application”). For the Examiner’s convenience, copies of the allowed claims in the ‘411 application and the pending claims in the ‘895 application are enclosed.

37 C.F.R. 41.202(a)(2)

Applicant believes that its claims 80-97 interfere with claims 52-54, 58, 60, 68, 69, 73, 98, 100, 101, 103, 105, and 106 of the ‘411 application and that claims 95-97 interfere with claims 1, 9, and 19 of the ‘895 application.

Applicant proposes the following counts:

1. Claim 80 of the present application or claim 52 of the '411 application;
2. Claim 91 of the present application or claim 98 of the '411 application;
3. Claim 95 of the present application or claim 1 of the '895 application;
4. Claim 96 of the present application or claim 9 of the '895 application; and
5. Claim 97 of the present application or claim 19 of the '895 application.

Applicant's claims 80-97 should be designated as corresponding to the proposed counts.

Specifically, claim 80 correspond to count 1. Claims 81-90 depend from claim 80 and specify narrower embodiments of the invention. Claim 91 corresponds to count 2. Claims 92-94 depend from claim 91 and specify narrower embodiments of the invention. Claim 95 corresponds to count 3. Claim 96 corresponds to count 4. Claim 97 corresponds to count 5.

Claims 52-54, 58, 60, 68, 69, 73, 95, 98, 100, 101, 103, 105, and 106 of the '411 application and claims 1, 9, and 19 of the '895 application should be designated as corresponding to one or more of the proposed counts. Claim 52 corresponds because it is literally one half of proposed count 1. Claim 98 corresponds because it is literally one half of proposed count 2. Claims 53, 54, 58, 60, 68, 69, 73, 95, 101, and 103 of the '411 application depend from claim 52 and are directed to the same patentable invention as proposed count 1. Claims 100, 105, and 106 of the '411 application depend from claim 98 and are directed to the same patentable invention as proposed count 2.

Claim 1 of the '895 corresponds because it is literally one half of proposed count 3.

Claim 9 of the '895 corresponds because it is literally one half of proposed count 4 and claim 19 of the '895 application corresponds because it is literally one half of proposed count 5. The field

of the invention defined by the claims of the present application and the claims of the '411 application and the '895 application is a brachytherapy seed comprising one or more polymeric structures that prevent or reduce migration of the seed and/or maintain orientation of the seed. The relevant time frame is just prior to September 19, 2002. As discussed below, that date is the earliest date to which Applicant claims benefit under 35 U.S.C. § 120.

Applicant's claim 80 is drawn to a therapeutic implant for use in brachytherapy comprising a metallic seed containing a radioactive material and a polymeric material molded to encapsulate the seed wherein an outer surface of the encapsulating polymeric material defines one or more ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation. Claim 52 of the '411 application is drawn to a therapeutic implant configured to be implanted in a similar manner as loose radioactive seeds are implanted, for use in brachytherapy having the same limitation as claim 80. Claims 80 and 52 correspond to count 1 for the reasons discussed above.

Applicant's claim 91 is drawn to a therapeutic implant, for use in brachytherapy, comprising a single radioactive seed that includes radioactive material contained within a metallic housing having a substantially smooth outer surface; and a polymeric material molded to completely encapsulate the metallic housing of the single radioactive seed wherein an outer surface of the encapsulating polymeric material includes a plurality of ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation; and

wherein the ribs are defined by variations in a thickness of the encapsulating polymeric material, not by an outer surface of the underlying metallic housing. Claim 98 of the '411 application is drawn to a therapeutic implant configured to be implanted in a similar manner as loose radioactive seeds are implanted, for use in brachytherapy having the same limitations as claim 91. Claims 91 and 98 correspond to count 2 for the reasons discussed above.

Applicant's claim 95 is drawn to an anchor mechanism to reduce a tendency for a structure to migrate or rotate after implantation of the structure into a patient, where the structure is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker. Claim 1 of the '895 application is drawn to an anchor mechanism to reduce a tendency for a structure to migrate or rotate after implantation of the structure into a patient, where the structure is one or more of a radioactive source, a thermal ablation implant, a spacer, a strand, or a radiopaque marker. Claims 95 and 1 correspond to count 3 for the reasons discussed above.

Applicant's claim 96 is drawn to a therapeutic implant, for use in brachytherapy. Claim 9 of the '895 application is drawn to a therapeutic member for use in brachytherapy and other radiation treatment. Claims 96 and 9 correspond to count 3 for the reasons discussed above.

Applicant's claim 97 is drawn to a method for using a therapeutic implant in brachytherapy. Claim 19 of the '895 application is drawn to a method for use in brachytherapy and other radiation treatment. Claims 97 and 19 correspond to count 3 for the reasons discussed above.

37 C.F.R. 41.202(a)(3)

Set forth below is a claim chart comparing Applicant's independent claims and the independent claims of the '411 and '895 applications to the proposed counts and showing why these claims interfere.

Count 1

<u>Claim 80 of the present application</u>	<u>Claim 52 of the '411 application</u>
<p>80. A therapeutic implant, for use in brachytherapy, comprising</p> <p style="padding-left: 40px;">a single radioactive seed that includes radioactive material contained within a metallic housing; and</p> <p style="padding-left: 40px;">a polymeric material molded to completely encapsulate the metallic housing of the single radioactive seed;</p> <p style="padding-left: 40px;">wherein an outer surface of the encapsulating polymeric material defines one or more ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation; and</p>	<p>52. A therapeutic implant configured to be implanted in a similar manner as loose radioactive seeds are implanted, for use in brachytherapy, comprising</p> <p style="padding-left: 40px;">a single radioactive seed that includes radioactive material contained within a metallic housing; and</p> <p style="padding-left: 40px;">a polymeric material molded to completely encapsulate the metallic housing of the single radioactive seed;</p> <p style="padding-left: 40px;">wherein an outer surface of the encapsulating polymeric material defines one or more ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a</p>

<p>wherein a thickness of the encapsulating polymeric material varies such that the thickness is greater where there is one of the one or more ribs than where there is not a rib.</p>	<p>tendency of the implant to migrate and rotate within a patient's body after implantation; and</p> <p>wherein a thickness of the encapsulating polymeric material varies such that the thickness is greater where there is one of the one or more ribs than where there is not a rib.</p>
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Count 2

<u>Claim 91 of the present application</u>	<u>Claim 98 of the '411 application</u>
<p>91. A therapeutic implant, for use in brachytherapy, comprising</p> <p>a single radioactive seed that includes radioactive material contained within a metallic housing having a substantially smooth outer surface; and</p> <p>a polymeric material molded to completely encapsulate the metallic housing of the single radioactive seed;</p> <p>wherein an outer surface of the</p>	<p>98. A therapeutic implant configured to be implanted in a similar manner as loose radioactive seeds are implanted, for use in brachytherapy, comprising</p> <p>a single radioactive seed that includes radioactive material contained within a metallic housing having a substantially smooth outer surface; and</p> <p>a polymeric material molded to completely encapsulate the metallic housing of</p>

<p>encapsulating polymeric material includes a plurality of ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation; and</p> <p>wherein the ribs are defined by variations in a thickness of the encapsulating polymeric material, not by an outer surface of the underlying metallic housing.</p>	<p>the single radioactive seed;</p> <p>wherein an outer surface of the encapsulating polymeric material includes a plurality of ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation; and</p> <p>wherein the ribs are defined by variations in a thickness of the encapsulating polymeric material, not by an outer surface of the underlying metallic housing.</p>
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Count 3

<u>Claim 95 of the present application</u>	<u>Claim 1 of the '895 application</u>
<p>95. An anchor mechanism to reduce a tendency for a structure to migrate or rotate after implantation of the structure into a patient, where the structure is one or more of a radioactive source, a spacer, a strand, or a</p>	<p>1. An anchor mechanism to reduce a tendency for a structure to migrate or rotate after implantation of the structure into a patient, where the structure is one or more of a radioactive source, a thermal ablation implant,</p>

<p>radiopaque marker, the anchor mechanism comprising:</p> <p>a sleeve to fit around the structure,</p> <p>the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve; and</p> <p>one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,</p>	<p>a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising:</p> <p>a sleeve to fit around the structure,</p> <p>the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve; and</p> <p>one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,</p>
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<p>wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.</p>	<p>wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.</p>
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Count 4

<u>Claim 96 of the present application</u>	<u>Claim 9 of the '895 application</u>
<p>96. A therapeutic implant, for use in brachytherapy comprising:</p> <p style="padding-left: 40px;">a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, and</p> <p style="padding-left: 40px;">an anchor mechanism comprising:</p> <p style="padding-left: 80px;">a sleeve to fit around the structure,</p> <p style="padding-left: 80px;">the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve; and</p> <p style="padding-left: 80px;">one or more protrusions extending from</p>	<p>9. A therapeutic member for use in brachytherapy and other radiation treatment, comprising:</p> <p style="padding-left: 40px;">a structure that is one or more of a radioactive source, a thermal ablation implant, a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising:</p> <p style="padding-left: 80px;">a sleeve to fit around the structure,</p> <p style="padding-left: 80px;">the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve; and</p>

<p>an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,</p> <p>wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.</p>	<p>one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,</p> <p>wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.</p>
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Count 5

<u>Claim 97 of the present application</u>	<u>Claim 19 of the '895 application</u>
<p>97. A method for using a therapeutic implant in brachytherapy comprising:</p> <p>providing a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, and</p> <p>an anchor mechanism comprising:</p> <p>fitting a sleeve to fit around the structure such that a portion of the structure extends out from each longitudinal end of the sleeve; wherein the sleeve includes one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions,</p> <p>loading the structure, with the sleeve</p>	<p>19. A method for use in brachytherapy and other radiation treatment comprising:</p> <p>Providing a structure that is one or more of a radioactive source, a thermal ablation implant, a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising:</p> <p>fitting a sleeve to fit around the structure such that a portion of the structure extends out from each longitudinal end of the sleeve; wherein the sleeve includes one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions,</p>

<p>around the structure, into a hollow needle; and</p> <p>using the hollow needle to implant the structure, with the sleeve around the structure, into patient tissue;</p> <p>wherein the patient tissue is caught in at the at least one space upon implantation of the structure, with the sleeve around the structure, to thereby reduce a tendency for the structure to migrate and rotate at implantation; and</p> <p>wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.</p>	<p>loading the structure, with the sleeve around the structure, into a hollow needle; and</p> <p>using the hollow needle to implant the structure, with the sleeve around the structure, into patient tissue;</p> <p>wherein the patient tissue is caught in at the at least one space upon implantation of the structure, with the sleeve around the structure, to thereby reduce a tendency for the structure to migrate and rotate at implantation; and</p> <p>wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.</p>
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Claim 80 of the present application and claim 52 of the '411 application interfere because the claims are directed to the same patentable invention. Both claims are directed to a therapeutic implant for brachytherapy comprising metallic radioactive seed encapsulated by a polymeric material molded wherein an outer surface of the encapsulating polymeric material defines one or more ribs having a substantially squared profile formed by a stepped portion

extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation. Claims 81-89 depend from claim 80 and interfere with claims 53, 54, 58, 60, 68, 69, 73, 95, 101, and 103 because the claims are directed to the same patentable invention.

Claim 91 of the present application and claim 98 of the '411 application interfere because the claims are directed to the same patentable invention. Both claims are directed to a therapeutic implant for brachytherapy comprising a metallic radioactive seed having a substantially smooth surface encapsulated by a polymeric material molded wherein an outer surface of the encapsulating polymeric material defines one or more ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation. Claims 92-94 depend from claim 91 and interfere with claims 100, 105, and 106 because the claims are directed to the same patentable invention.

Claim 95 of the present application and claim 1 of the '895 application interfere because the claims are directed to the same patentable invention. Both claims are directed to an anchoring mechanism to reduce the tendency for a structure to migrate or rotate after implantation of the structure into a patient, where the structure is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, the anchoring structure comprising a sleeve to fit around the structure, the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve; and one or more protrusions extending from an outer surface

of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation.

Claim 96 of the present application and claim 9 of the '895 application interfere because the claims are directed to the same patentable invention. Both claims are directed to a therapeutic member for use in brachytherapy and other radiation treatment, comprising a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, and an anchor mechanism comprising a sleeve to fit around the structure, the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve; and one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation.

Claim 97 of the present application and claim 19 of the '895 application interfere because the claims are directed to the same patentable invention. Both claims are directed to a method

for use in brachytherapy and other radiation treatment comprising providing a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, and an anchor mechanism comprising fitting a sleeve to fit around the structure such that a portion of the structure extends out from each longitudinal end of the sleeve; wherein the sleeve includes one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions, loading the structure, with the sleeve around the structure, into a hollow needle; and using the hollow needle to implant the structure, with the sleeve around the structure, into patient tissue wherein the patient tissue is caught in at the at least one space upon implantation of the structure, with the sleeve around the structure, to thereby reduce a tendency for the structure to migrate and rotate at implantation.

37 C.F.R. 41.202(a)(4)

Applicant will likely prevail on priority because the effective filing date is prior to the effective filing date of the '411 and '895 applications. The present application was filed on September 19, 2003 and is a continuation in part of U.S.S.N. 09/861,326, filed on May 18, 2001, which claims priority to U.S.S.N. 60/249,128, filed on November 16, 2000. The present application also claims priority to U.S.S.N. 60/412,050, filed on September 19, 2002. As discussed below, the '050 application provides a construction reduction to practice of at least one embodiment within the scope of the counts.

In contrast, the '411 and the '895 applications were filed on July 22, 2005. The '411 and '895 applications do not claim priority to an earlier filed application under 35 U.S.C. §§ 119 or 120.

Applicant is Senior Party by at least three years. This shifts the burden to the Junior Party to prove conception and reduction to practice.

37 C.F.R. 41.202(a)(5)

Set forth below is a claim chart showing the written description for claims 80-97 of the present application in the application as originally filed. Reference is made to the paragraph number in the published application.

<u>Claim</u>	<u>Specification</u>
80. A therapeutic implant, for use in brachytherapy	paragraph 0002, which discloses that the application relates to implantable brachytherapy devices
a single metallic radioactive seed that includes radioactive material contained within a metallic housing	paragraphs 0039, 0088, and 0094 (disclose that the seeds described therein can be made of a biocompatible substance, such as titanium or stainless steel)
polymeric material which encapsulates the metallic housing of the single seed	paragraph 0048 (discloses polymers can be used to form, or to coat, strands; seed and strand are used interchangeably through out the specification, see for example paragraphs 0054 and 0065, and paragraph 0089, which discloses diameters and lengths of conventional seeds), and paragraphs 0048 (polymers can be used to coat devices), 0083 (film coating of seeds or strands) 0084 (uniform coating and partial coating) 0085 (coating material), and 0092 and Figure 2 (enveloping a strand with a sleeve formed from a polymeric material)
wherein an outer surface of the encapsulating polymeric material defines one or more ribs having a substantially squared profile formed	Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending

<p>by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation and wherein a thickness of the encapsulating polymeric material varies such that the thickness is greater where there is one of the one or more ribs than where there is not a rib</p>	<p>between a pair of sidewalls), paragraph 0119 (discloses the use of a polymeric material to form ring-shaped structures around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), paragraph 0090 (discloses one or more cavities or pores to increase the surface area of the strand exposed to the target tissue – this can be construed as structures with a "stepped portion" where portions of the polymer coating are thicker than other portions), and paragraph 0103 (discloses that the radiopaque marker can take the form of two bands or rings placed at two locations along the outer surface of the cylindrical strand or seed; suitable radiopaque markers include polymeric radiopaque markers, as disclosed at paragraph 0105)</p> <p>Paragraph 0092 discloses that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably. Further, the disclosure that the hollow tube can have any length encompasses rings, bands, or ribs of polymer. Discrete section can be formed by molding or adhering the polymer to the seed or strand (paragraph 0100). Paragraph 0118 describes ridges</p>
<p>81. The implant of claim 80, wherein the one or more ribs are made from the polymeric material that encapsulates the metallic material of the single radioactive seed</p>	<p>Figure 3D (discloses ribs or fins formed from a polymeric material) and paragraphs 0103 and 0105 (disclose rings or bands of a polymeric radiopaque marker)</p>
<p>82. The implant of claim 81, wherein the polymeric material is bioabsorbable</p>	<p>paragraph 0094 (discloses that the polymeric material can be biodegradable)</p>
<p>83. The implant of claim 80, wherein the one or more ribs are defined by a shape of a mold</p>	<p>Paragraph 0092 and Figure 3D. Paragraph 0092 discloses that the polymeric material can</p>

that is used to encapsulate the seed	be in the form of a sleeve which envelopes the seed or strand. Figure 3D shows a seed or strand having one or more ribs. The polymeric material containing the ribs can be a sleeve as described in paragraph 0092. Paragraph 0100 discloses molding the polymeric material.
84. The implant of claim 80, wherein the one or more ribs form one or more rings or a helix about the radial circumference of the metallic housing of the radioactive seed	paragraphs 0103, 0105, and 0120 as discussed above with respect to claim 80
85. The implant of claim 80, wherein the thickness of the encapsulating polymeric material that encapsulates the metallic housing of the single radioactive seed is at least 0.002 inches.	paragraphs 0087-0089
86. The implant of claim 80, wherein at least one of the one or more ribs extends at least 0.002 inches beyond portions of the encapsulating polymeric material where there is not a rib.	paragraphs 0087-0089
87. The implant of claim 80, wherein the metallic housing of the single radioactive seed includes first and second longitudinal ends, and wherein the one or more ribs are located between the longitudinal ends of the metallic housing of the single radioactive seed	paragraph 0039, 0103, 0105, and 0120, for the reasons discussed above with respect to claim 80
88. The implant of claim 80, wherein the metallic housing of the single radioactive seed has a substantially smooth outer surface, without any protrusions, that is completely encapsulated by the polymeric material.	paragraphs 0005, 0039, and 0094
89. The implant of claim 80, wherein the polymeric material is bioadhesive	paragraphs 0107-0112 and Figure 6 (discloses polyimide hairs or setae, which are bioadhesive)
90. The implant of claim 80, wherein the biomaterial is bio-adherent	paragraphs 0107-0112 and Figure 6 (discloses polyimide hairs or setae, which are

	bioadhesive)
91. A therapeutic implant, for use in brachytherapy, comprising	paragraph 0002, which discloses that the application relates to implantable brachytherapy devices
a single radioactive seed that includes radioactive material contained within a metallic housing having a substantially smooth outer surface; and	paragraphs 0039, 0088, and 0094 (disclose that the seeds described therein can be made of a biocompatible substance, such as titanium or stainless steel)
a polymeric material molded to completely encapsulate the metallic housing of the single radioactive seed	paragraph 0048 (discloses polymers can be used to form, or to coat, strands; seed and strand are used interchangeably though out the specification, see for example paragraphs 0054 and 0065, and paragraph 0089, which discloses diameters and lengths of convention seeds), and paragraphs 0048 (polymers can be used to coat devices), 0083 (film coating of seeds or strands) 0084 (uniform coating and partial coating) 0085 (coating material), and 0092 and Figure 2 (enveloping a strand with a sleeve formed from a polymeric material)
wherein an outer surface of the encapsulating polymeric material includes a plurality of ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation and wherein the ribs are defined by variations in a thickness of the encapsulating polymeric material, not by an outer surface of the underlying metallic housing	Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), paragraph 0119 (discloses the use of a polymeric material to form ring-shaped structures around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), paragraph 0090 (discloses one or more cavities or pores to increase the surface area of the strand exposed to the target tissue – this can be construed as structures with a "stepped portion" where portions of the polymer coating are thicker than other portions), and paragraph 0103 (discloses that the radiopaque marker can take the form of two bands or rings placed at two locations along the outer surface of the cylindrical strand or seed; suitable radiopaque

	<p>markers include polymeric radiopaque markers, as disclosed at paragraph 0105)</p> <p>Paragraph 0092 discloses that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably. Further, the disclosure that the hollow tube can have any length encompasses rings, bands, or ribs of polymer. Discrete section can be formed by molding or adhering the polymer to the seed or strand (paragraph 0100). Paragraph 0118 describes ridges</p>
92. The implant of claim 91, wherein the polymeric material is bioadhesive	paragraphs 0107-0112, which discloses polyimide hairs or setae, which are bioadhesive
93. The implant of claim 91, wherein the biomaterial is bio-adherent	paragraphs 0107-0112, which discloses polyimide hairs or setae, which are bioadhesive
94. The implant of claim 91, wherein a thickness of the encapsulating polymeric material varies such that the thickness is greater where there is a the rib than where there is not a rib	Figure 3D

<u>Claims</u>	<u>Specification</u>
95. An anchor mechanism to reduce a tendency for a structure to migrate or rotate after implantation of the structure into a patient, where the structure is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising:	paragraphs 0017 (strand), 0033 and 0039 (seed containing a radioactive material, i.e., radioactive source), and 0105 (polymeric radiopaque marker)
a sleeve to fit around the structure, the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of	paragraphs 0048 (discloses polymers can be used to form, or to coat, strands; seed and strand are used interchangeably though out the specification, see for example paragraphs 0054

<p>the structure extends out from each longitudinal end of the sleeve</p>	<p>and 0065, and paragraph 0089, which discloses diameters and lengths of convention seeds), and 0048 (polymers can be used to coat devices), 0083 (film coating of seeds or strands), 0084 (uniform coating and partial coating), 0085 (coating material), 0092 and Figure 2 (enveloping a strand with a sleeve formed from a polymeric material), and Paragraph 0092 discloses that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably</p>
<p>one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,</p>	<p>Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), paragraph 0119 (discloses the use of a polymeric material to form ring-shaped structures around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a “rib-like” effect, i.e., squared off areas of polymer that are thicker than adjoining areas), paragraph 0090 (discloses one or more cavities or pores to increase the surface area of the strand exposed to the target tissue – this can be construed as structures with a “stepped portion” where portions of the polymer coating are thicker than other portions), and paragraph 0103 (discloses that the radiopaque marker can take the form of two bands or rings placed at two locations along the outer surface of the cylindrical strand or seed; suitable radiopaque markers include polymeric radiopaque markers, as disclosed at paragraph 0105)</p>
<p>wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.</p>	<p>Figure 3D</p>

<p>96. A therapeutic implant, for use in brachytherapy, comprising: a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, and an anchor mechanism comprising:</p>	<p>paragraphs 0017 (strand), 0033 and 0039 (seed containing a radioactive material, i.e., radioactive source), and 0105 (polymeric radiopaque marker)</p>
<p>a sleeve to fit around the structure, the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve</p>	<p>paragraphs 0048 (discloses polymers can be used to form, or to coat, strands; seed and strand are used interchangeably though out the specification, see for example paragraphs 0054 and 0065, and paragraph 0089, which discloses diameters and lengths of convention seeds), and 0048 (polymers can be used to coat devices), 0083 (film coating of seeds or strands), 0084 (uniform coating and partial coating), 0085 (coating material), 0092 and Figure 2 (enveloping a strand with a sleeve formed from a polymeric material), and Paragraph 0092 discloses that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably</p>
<p>one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,</p>	<p>Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), paragraph 0119 (discloses the use of a polymeric material to form ring-shaped structures around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a “rib-like” effect, i.e., squared off areas of polymer that are thicker than adjoining areas), paragraph 0090 (discloses one or more cavities or pores to increase the surface area of the strand exposed to the target tissue – this can be construed as structures with a “stepped portion” where</p>

	portions of the polymer coating are thicker than other portions), and paragraph 0103 (discloses that the radiopaque marker can take the form of two bands or rings placed at two locations along the outer surface of the cylindrical strand or seed; suitable radiopaque markers include polymeric radiopaque markers, as disclosed at paragraph 0105)
wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.	Figure 3D
97. A method for using a therapeutic implant, in brachytherapy comprising: providing a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, and an anchor mechanism comprising:	paragraphs 0017 (strand), 0033 and 0039 (seed containing a radioactive material, i.e., radioactive source), and 0105 (polymeric radiopaque marker) and paragraph 0018 (administration by needle).
fitting a sleeve to fit around the structure such that a portion of the structure extends out from each longitudinal end of the sleeve	paragraphs 0048 (discloses polymers can be used to form, or to coat, strands; seed and strand are used interchangeably though out the specification, see for example paragraphs 0054 and 0065, and paragraph 0089, which discloses diameters and lengths of convention seeds), and 0048 (polymers can be used to coat devices), 0083 (film coating of seeds or strands), 0084 (uniform coating and partial coating), 0085 (coating material), 0092 and Figure 2 (enveloping a strand with a sleeve formed from a polymeric material), and Paragraph 0092 discloses that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably
wherein the sleeve includes one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or	Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), paragraph 0119

more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions	(discloses the use of a polymeric material to form ring-shaped structures around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a “rib-like” effect, i.e., squared off areas of polymer that are thicker than adjoining areas), paragraph 0090 (discloses one or more cavities or pores to increase the surface area of the strand exposed to the target tissue – this can be construed as structures with a “stepped portion” where portions of the polymer coating are thicker than other portions), and paragraph 0103 (discloses that the radiopaque marker can take the form of two bands or rings placed at two locations along the outer surface of the cylindrical strand or seed; suitable radiopaque markers include polymeric radiopaque markers, as disclosed at paragraph 0105)
loading the structure, with the sleeve around the structure, into a hollow needle; and using the hollow needle to implant the structure, with the sleeve around the structure, into patient tissue;	Paragraph 0018
wherein the patient tissue is caught in at the at least one space upon implantation of the structure, with the sleeve around the structure, to thereby reduce a tendency for the structure to migrate and rotate at implantation	Paragraphs 0018, 0101, 0118, 0119, and 0121
wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.	Figure 3D

37 C.F.R. 41.202 (a)(6)

Applicant's disclosure in the present application provides a constructive reduction to practice within the scope of the interfering subject matter as described in the table above under 37 C.F.R. 41.202 (a)(5).

The present application claims priority to provisional application U.S.S.N. 60/412,050, filed September 19, 2002. Set forth below is a claim chart showing where the disclosure of the '050 application provides a constructive reduction to practice within the scope of the interfering subject matter.

<u>Claim</u>	<u>Specification of the '050 application</u>
80. A therapeutic implant, for use in brachytherapy	Page 1, lines 8 and 9, which discloses that the application relates to implantable brachytherapy devices
a single metallic radioactive seed that includes radioactive material contained within a metallic housing	Page 19, lines 27-30 (disclose that the seeds described therein can be made of a biocompatible substance, such as titanium or stainless steel)
polymeric material which encapsulates the metallic housing of the single seed	Page 18, lines 4-11 page 20, lines 2-4, page 27, lines 19-28, page 28, lines 1-6, and page 32, line 20 to page 33, line 18 and Figure 2
wherein an outer surface of the encapsulating polymeric material defines one or more ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation and wherein a thickness of the encapsulating polymeric material varies such that the thickness is greater where there is one of the one or more ribs than where there is not a rib	Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), Figure 3E and page 34, lines 24-27 (seed containing a radiopaque marker in the form of a band or rings around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), markers, as disclosed at paragraph 0105) Page 28, lines 1-4 disclose that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably. Further, the disclosure that the hollow tube can have any length encompasses rings, bands, or ribs of polymer. Discrete section can be formed by molding or

	adhering the polymer to the seed or strand
81. The implant of claim 80, wherein the one or more ribs are made from the polymeric material that encapsulates the metallic material of the single radioactive seed	Figure 3D (discloses ribs or fins formed from a polymeric material) Figure 3E and page 34, lines 24-27 (disclose rings or bands of a polymeric radiopaque marker)
82. The implant of claim 81, wherein the polymeric material is bioabsorbable	Page 35, lines 11 and 12
83. The implant of claim 80, wherein the one or more ribs are defined by a shape of a mold that is used to encapsulate the seed	Figure 3D and 3E. Paragraph 0092 discloses that the polymeric material can be in the form of a sleeve which envelopes the seed or strand. Figure 3D shows a seed or strand having one or more ribs. The polymeric material containing the ribs can be a sleeve as described above
84. The implant of claim 80, wherein the one or more ribs form one or more rings or a helix about the radial circumference of the metallic housing of the radioactive seed	Figure 3E and page 34, lines 24-27 (disclose rings or bands of a polymeric radiopaque marker)
85. The implant of claim 80, wherein the thickness of the encapsulating polymeric material that encapsulates the metallic housing of the single radioactive seed is at least 0.002 inches.	Pages 10, lines 11-18 and page 26, line 15 to page 27, line 5
86. The implant of claim 80, wherein at least one of the one or more ribs extends at least 0.002 inches beyond portions of the encapsulating polymeric material where there is not a rib.	Pages 10, lines 11-18 and page 26, line 15 to page 27, line 5
87. The implant of claim 80, wherein the metallic housing of the single radioactive seed includes first and second longitudinal ends, and wherein the one or more ribs are located between the longitudinal ends of the metallic housing of the single radioactive seed	Figure 3E and page 34, lines 24-27 (disclose rings or bands of a polymeric radiopaque marker)
88. The implant of claim 80, wherein the metallic housing of the single radioactive seed has a substantially smooth outer surface,	Page 19, lines 27-30 (disclose that the seeds described therein can be made of a biocompatible substance, such as titanium or

without any protrusions, that is completely encapsulated by the polymeric material.	stainless steel)
91. A therapeutic implant configured to be implanted in a similar manner as loose radioactive seeds are implanted, for use in brachytherapy, comprising	Page 1, lines 8 and 9, which discloses that the application relates to implantable brachytherapy devices
a single radioactive seed that includes radioactive material contained within a metallic housing having a substantially smooth outer surface; and	Page 19, lines 27-30 (disclose that the seeds described therein can be made of a biocompatible substance, such as titanium or stainless steel)
a polymeric material molded to completely encapsulate the metallic housing of the single radioactive seed	Page 18, lines 4-11 page 20, lines 2-4, page 27, lines 19-28, page 28, lines 1-6, and page 32, line 20 to page 33, line 18 and Figure 2
wherein an outer surface of the encapsulating polymeric material includes a plurality of ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation and wherein the ribs are defined by variations in a thickness of the encapsulating polymeric material, not by an outer surface of the underlying metallic housing	<p>Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), Figure 3E and page 34, lines 24-27 (seed containing a radiopaque marker in the form of a band or rings around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), markers, as disclosed at paragraph 0105)</p> <p>Page 28, lines 1-4 disclose that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably. Further, the disclosure that the hollow tube can have any length encompasses rings, bands, or ribs of polymer. Discrete section can be formed by molding or adhering the polymer to the seed or strand</p>

94. The implant of claim 91, wherein a thickness of the encapsulating polymeric material varies such that the thickness is greater where there is a the rib than where there is not a rib	Figure 3D
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<u>Claims</u>	<u>Specification</u>
95. An anchor mechanism to reduce a tendency for a structure to migrate or rotate after implantation of the structure into a patient, where the structure is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising:	Figure 3D, Page 1, lines 8 and 9, Figure 3E and page 34, lines 24-27.
a sleeve to fit around the structure, the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve	Page 18, lines 4-11 page 20, lines 2-4, page 27, lines 19-28, page 28, lines 1-6, and page 32, line 20 to page 33, line 18 and Figure 2
one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,	Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), Figure 3E and page 34, lines 24-27 (seed containing a radiopaque marker in the form of a band or rings around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas, markers) Page 28, lines 1-4 disclose that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used

	interchangeably. Further, the disclosure that the hollow tube can have any length encompasses rings, bands, or ribs of polymer. Discrete section can be formed by molding or adhering the polymer to the seed or strand
wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.	Figure 3D
96. A therapeutic member for use in brachytherapy and other radiation treatment, comprising: a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising:	Figure 3D, Page 1, lines 8 and 9, Figure 3E and page 34, lines 24-27.
a sleeve to fit around the structure, the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve	Page 18, lines 4-11 page 20, lines 2-4, page 27, lines 19-28, page 28, lines 1-6, and page 32, line 20 to page 33, line 18 and Figure 2
one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,	<p>Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), Figure 3E and page 34, lines 24-27 (seed containing a radiopaque marker in the form of a band or rings around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), markers)</p> <p>Page 28, lines 1-4 disclose that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used</p>

	interchangeably. Further, the disclosure that the hollow tube can have any length encompasses rings, bands, or ribs of polymer. Discrete section can be formed by molding or adhering the polymer to the seed or strand
wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.	Figure 3D
97. A method for use in brachytherapy and other radiation treatment comprising: providing a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising:	Figure 3D, Page 1, lines 8 and 9, Figure 3E and page 34, lines 24-27.
fitting a sleeve to fit around the structure such that a portion of the structure extends out from each longitudinal end of the sleeve	Page 18, lines 4-11 page 20, lines 2-4, page 27, lines 19-28, page 28, lines 1-6, and page 32, line 20 to page 33, line 18 and Figure 2
wherein the sleeve includes one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions	<p>Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), Figure 3E and page 34, lines 24-27 (seed containing a radiopaque marker in the form of a band or rings around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), markers)</p> <p>Page 28, lines 1-4 disclose that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably. Further, the disclosure that the hollow tube can have any length encompasses rings, bands, or ribs of polymer.</p>

	Discrete section can be formed by molding or adhering the polymer to the seed or strand
loading the structure, with the sleeve around the structure, into a hollow needle; and using the hollow needle to implant the structure, with the sleeve around the structure, into patient tissue;	Page 26, lines 5-30 and page 27, lines 6-8.
wherein the patient tissue is caught in at the at least one space upon implantation of the structure, with the sleeve around the structure, to thereby reduce a tendency for the structure to migrate and rotate at implantation	Page 26, lines 1-5
wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.	Figure 3D, Figure 3E, and page 34, lines 24-27

Respectfully submitted,

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